NRC FORM 591M PART 1
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
BAMF Health 109 Michigan St. NW Grand Rapids, Michigan 49503 REPORT NO.: 2022-001	Region III U.S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER	4. LICENSE NUMBER	5. DATE OF INSPECTION
030-39267	21-35632-01	July 19, 2022

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☑ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violations closed.

☐ 3. The violations, specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy to exercise discretion, were satisfied.

☐ Non-Cited Violation was/were discussed involving the following requirement(s) and Corrective Action(s):

☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE	Mark Sitek, RSO		7-19-2022
NRC INSPECTOR	Jason Dykert, Health Physicist		7-19-22
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Geoffrey M. Warren	Digitally signed by Geoffrey M. Warren Date: 2022.08.10 10:22:14 -05'00'

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
BAMF Health	030-39267	21-35632-01

4. Report Number(s):	5. Date(s) of Inspection:
2022-001	July 19, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Jason Dykert	03210	2	IP 87125

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Mark Sitek, RSO Colton Conrad, AU, onsite RSO	mark.sitek@bamfhealth.com colton.conrad@bamfhealth.com	949-939-2641 N/A

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☑ Initial	☑ Main Office ☐ Field Office	07/19/2024
☐ Routine ☑ Announced	☐ Temporary Job Site ☐ Remote	☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced		☐ Reduced ☐ No change

16. Scope and Observations:

This was an initial inspection of BAMF Health's proton accelerator isotope production license. The six authorized users of the GE PETtrace-890 cyclotrons were engineering staff, production users, and an onsite RSO. The isotopes produced were primarily fluorine-18, carbon-11, nitrogen-13, oxygen-15, and gallium-68 for use under BAMF's radiopharmacy and nuclear medicine NRC licenses (docket nos. 030-39300 and 030-39295).

The inspection consisted of interviews with select licensee personnel, demonstrations and observations of licensed activities, review of selected records, walk-downs and surveys of public areas above the cyclotron and the facility during production, and independent surveys. The licensee's facility was secured from unauthorized access, and laboratory dress requirements and controls were in place for accessing the cyclotron areas. The inspector toured the area and observed the onsite RSO perform a vault room check for personnel, clear the safety switches in the cyclotron room, and test the interlock function of the vault door. The interlocks functioned correctly, and the cyclotron did not operate if the door was not in the closed position. The inspector observed the area controls and operating indicators when the cyclotron was in-use and production of an isotope was observed without issue.

The inspector observed the filters and pressure or temperature sensors on the facility exhaust systems, associated ROTEM radiation monitors, and the cyclotron engineers' checklist for proper system parameters completed prior to operation. Ventilation exhaust monitoring records were reviewed demonstrating ALARA effluent air releases within limits. The carbon filter banks and delay maze differential pressure measurements were in an acceptable range. Daily surveys and wipes of areas, cold trash surveyed prior to disposal, and production accounting for use, transfer, decay and disposal was properly documented. The licensee's storage of accelerator parts was adequately posted and locked. Transfer mechanisms from the cyclotron vaults to the hot cells and fume hoods, used under the NRC radiopharmacy license for medical isotope production, were as described in the license tie-down documents.

Physical inventory and leak tests of sealed check sources were documented appropriately. The inspector observed the authorized users wearing appropriate occupational dosimetry, no unusual doses were noted in the records. The licensee's safe operating and emergency procedures were reviewed, procedures were developed and maintained as required. Emergency spill kits were available and annual emergency drills were conducted. Area radiation monitors were placed strategically around the building. The inspector performed independent surveys and concluded that the licensee's dose rate survey records and area postings were adequate.

No violations of NRC requirements were identified as a result of this inspection.